

40 Sub
F1
We Claim:

1. A method for producing a tropoelastin biomaterial fused onto a tissue substrate comprising:
providing a layer of tropoelastin biomaterial
5 having a first and second outer major surface and a tissue substrate having a first and second outer major surface; and

applying an energy absorbing material, which is energy absorptive within a predetermined range of light
10 wavelengths, to a selected one of said first and second outer surfaces of the tropoelastin biomaterial in an amount which will cause fusing together of one of said first and second outer surfaces of the
15 tropoelastin biomaterial and one of said first and second outer surfaces of said tissue substrate, said energy absorbing material penetrating into the interstices of said tropoelastin biomaterial;

irradiating the energy absorbing material with light energy in said predetermined wavelength range
20 with an intensity sufficient to fuse together one of said first and second outer surfaces of the tropoelastin biomaterial and the tissue substrate; and fusing together the selected one of said first and second outer surfaces of the tropoelastin biomaterial
25 and the tissue substrate.

2. The method of claim 1, which further includes the step of indirectly irradiating said energy absorbing material by directing the light energy first through the tropoelastin biomaterial or tissue
30 substrate and then to the energy absorbing material.

3. The method of claim 1, wherein said energy absorbing Material comprises a biocompatible chromophore.

5 4. The method of claim 1, wherein said energy absorbing material comprises an energy absorbing dye.

6 SF
7
8
9
10 5. The method of claim 1, which further includes the step of substantially dissipating said energy absorbing material when said tropoelastin biomaterial and said tissue substrate are fused together.

11
12
13
14 6. The method of claim 1, which further includes the step of staining the first or second surface of said tropoelastin biomaterial with said energy absorbing material.

15 7. The method of claim 1, which further includes the step of applying said energy absorbing material to one of said outer surfaces of said biomaterial by doping a separate tropoelastin layer with an energy absorbing material, and then fusing the doped separate tropoelastin layer to the tropoelastin biomaterial.

16
17
18
19
20 8. The method of claim 1, wherein the energy absorbing layer is substantially uniformly applied to a selected one of said first and second outer surfaces of the tropoelastin biomaterial.

21
22
23
24
25 9. The method of claim 1, which further includes the step of covering substantially the entire outer surface of the tropoelastin biomaterial with the energy absorbing material.

26
27
28
29
30 10. The method of claim 1, which further includes the step of irradiating the energy absorbing material with light energy at a localized temperature of from

about 40 to 600 degrees C. for period of time
sufficient to cause fusing together of one of said
first and second outer surfaces of the tropoelastin
biomaterial and one of said first and second outer
surfaces of said tissue substrate.

11. The method of claim 1, wherein the tissue
substrate is a live tissue substrate.

12. The method of claim 1, wherein the average
thickness of the energy absorbing material which
penetrates into the interstices of the tropoelastin
biomaterial is from about 0.5 to 300 microns.

13. The method of claim 1, which further includes
the step of arranging the magnitude of the wave length,
energy level, absorption, and light intensity during
irradiation with light energy of the energy absorbing
material, and the concentration of the energy absorbing
material, so that the localized temperature at the
interface of said first and second outer surfaces of
the tropoelastin biomaterial and the tissue substrate
are maintained at from about 40 to 600 °C., thereby
fusing together the tropoelastin biomaterial and the
tissue substrate.

14. The method of claim 1, wherein the tissue
substrate so that the tissue substrate is a live tissue
substrate.

15. The method of claim 1, which further includes
the step of employing tropoelastin material for use in
replacement or repair of bladders, intestines, tubes,
esophagus, ureters, arteries, veins, stomachs, lungs,
hearts, colons, skin, or as a cosmetic implantation.

523
047

5

2

Sub

16. The method of claim 1, which further includes the step of forming an tropoelastin into a three-dimensional support structure wherein said tropoelastin material is combined with a stromal support matrix populated with actively growing stromal cells.

17. The method of claim 1, wherein said stromal support matrix comprise fibroblasts.

523
047

10

18. The method of claim 1, which further includes the step of forming a cellular lining of human cells on one of the major surfaces of said tropoelastin layer.

19. The method of claim 1, wherein said cells which are employed to form such a lining are at least one of endothelial cells, epithelial cells and urothelial cells.

15

20. The method of claim 1, which further includes the step of forming an tropoelastin biocompatible inner lining for mechanical human structures to ensure their continued internal use in a human body.

20

Sub

21. The method of claim 20, wherein the biocompatible inner lining is employed in heart valves, heart implants, dialysis equipment, or oxygenator tubing for heart-lung by-pass systems.

25

22. The method of claim 1, which includes the step of incorporating a drug into said biomaterial thereby decreasing the need for systemic intravenous or oral medications.

23. A method for using an tropoelastin biomaterial comprising:

providing a layer of tropoelastin biomaterial having a first and second outer major surface which is tissue-fusible;

providing a tissue substrate having a first and second outer major surface;

applying an energy absorbing material, which is energy absorptive within a predetermined range of light wavelengths, to one of said first and second outer surfaces of the tropoelastin biomaterial in an amount which will cause fusing together of one of said first and second outer surfaces of the tropoelastin biomaterial and one of said first and second outer surfaces of said tissue substrate, said energy absorbing material penetrating into the interstices of said tropoelastin biomaterial;

irradiating the energy absorbing material with light energy in said predetermined wavelength range with an intensity sufficient to fuse together one of said first and second outer surfaces of the tropoelastin biomaterial and the tissue substrate; and

fusing together one of said first and second outer surfaces of the tropoelastin biomaterial and the tissue substrate.

24. A method for producing an tropoelastin biomaterial fused onto a tissue substrate comprising:

providing a layer of tropoelastin biomaterial having a first and second outer major surface and a tissue substrate having a first and second outer major surface; and

applying an energy absorbing material, which is energy absorptive within a predetermined range of light wavelengths, to one of said first and second outer surfaces of the tropoelastin biomaterial in an amount which will cause fusing together of one of said first and second outer surfaces of the tropoelastin biomaterial and one of said outer surface of said tissue substrate, said energy absorbing material penetrating into the interstices of said tropoelastin biomaterial;

indirectly irradiating the energy absorbing material by directing the light energy first through the tropoelastin biomaterial or tissue substrate and then to the energy absorbing material, said light energy being in said predetermined wavelength range with an intensity sufficient to fuse together one of said first and second outer surfaces of the crosslinked tropoelastin biomaterial and the outer surface of said tissue substrate; and

fusing together one of said first and second outer surfaces of the crosslinked tropoelastin biomaterial and the outer surface of said tissue substrate and substantially dissipating said energy absorbing material when said crosslinked tropoelastin biomaterial and said tissue substrate are fused together.

25. A prosthetic device comprising:

a support member comprising a stent, a conduit or a scaffold; and

a layer of a tropoelastin biomaterial located on said support member.

26. The prosthetic device of claim 25, wherein the layer of said tropoelastin biomaterial completely surrounds said support member.

27. The prosthetic device of claim 25, wherein said support member is formed of a metal.

28. The prosthetic device of claim 25, wherein said support member is formed of a synthetic material.

29. The prosthetic device of claim 25, wherein said synthetic material comprises a polymeric material.

30. The prosthetic device of claim 25, wherein said polymeric material is selected from a group consisting of polyethylene terephthalate (Dacron), Gore-tex, teflon, polyolefin copolymer, polyurethane and polyvinyl alcohol.

31. The prosthetic device of claim 25, wherein said support member is formed from a hybrid polymer comprising a synthetic polymeric material and a natural polymeric material including tropoelastin.

32. The prosthetic device of claim 25, wherein said support member is formed from a biological material.

33. The prosthetic device of claim 25, wherein said biological material comprises collagen.

34. The prosthetic device of claim 25, wherein the layer of tropoelastin material comprises a covering, a coating, or a lining for said support member.

35. The prosthetic device of claim 25, which is implantable within a vessel, an artery, a vein, an

esophagus, a liver, an intestine, a colon, a ureter, a urethra, or a fallopian tube.

36. A method for producing a prosthetic device comprising:

providing a layer of tropoelastin biomaterial and a support member comprising a stent, a conduit or a scaffold; and

applying said layer of tropoelastin biomaterial to said support member to form said prosthetic device.

37. The method of claim 36, which includes the step of applying the layer of said tropoelastin biomaterial so that it surrounds said support member.

38. The method of claim 36, which includes the step of forming said tropoelastin biomaterial by polymerization.

39. The method of claim 36, which includes the step of molding said tropoelastin biomaterial of a suitable size and shape.

40. The method of claim 36, which includes the step of cross-linking the polymerized tropoelastin biomaterial by cross-linking using gamma radiation or through the use of a cross-linking agent.

41. The method of claim 36, which includes the step of forming said tropoelastin biomaterial into a sheet or tube, and then covering said support with said sheet.

42. The method of claim 36, which includes the step of attaching said sheet to said support by grafting.

43. The method of claim 36, which includes the step of attaching said sheet to said support by mechanical bonding.

44. The method of claim 37, which includes the step of attaching said sheet to said support by laser bonding.

45. The method of claim 36, which includes the step of incorporating a drug into said layer of tropoelastin material thereby decreasing the need for systemic intravenous or oral medications.

46. The method of claim 36, wherein said support member comprises titanium, tantalum, stainless steel or nitinol.

47. A method for producing a tropoelastin biomaterial, which comprises:
providing a tropoelastin monomer;
polymerizing said tropoelastin monomer to form a tropoelastin polymer; and

forming a biocompatible tropoelastin biomaterial from said tropoelastin polymer for use in biomedical applications.

48. The method of claim 47, which further includes the step of employing tropoelastin material for use in replacement or repair of bladders, intestines, tubes, esophagus, ureters, arteries, veins, stomachs, lungs, hearts, colons, skin, or as a cosmetic implantation.

49. The method of claim 47, which further includes the step of forming an tropoelastin into a three-dimensional support structure wherein said

tropoelastin material is combined with a stromal support matrix populated with actively growing stromal cells.

50. The method of claim 47, wherein said stromal support matrix comprise fibroblasts.

51. The method of claim 47, which further includes the step of forming a cellular lining of human cells on one of the major surfaces of said tropoelastin layer.

52. The method of claim 47, wherein said cells which are employed to form such a lining are at least one of endothelial cells, epithelial cells and urothelial cells.

53. The method of claim 47, which further includes the step of forming an tropoelastin biocompatible inner lining for mechanical human structures to ensure their continued internal use in a human body.

54. The method of claim 47, wherein the biocompatible inner lining is employed in heart valves, heart implants, dialysis equipment, or oxygenator tubing for heart-lung by-pass systems.

55. The method of claim 47, which includes the step of incorporating a drug into said biomaterial thereby decreasing the need for systemic intravenous or oral medications.

56. A method for using a tropoelastin polymer, which comprises:

providing a tropoelastin monomer;

polymerizing said tropoelastic monomer to form
said tropoelastin polymer;
forming a biocompatible tropoelastin biomaterial
from said tropoelastin polymer; and
5 using said biocompatible tropoelastin biomaterial
in biomedical applications.

57. The method of claim 56, which further
includes the step of employing tropoelastin material
for use in replacement or repair of bladders,
10 intestines, tubes, esophagus, ureters, arteries, veins,
stomachs, lungs, hearts, colons, skin, or as a cosmetic
implantation.

58. The method of claim 56, which further
includes the step of forming an tropoelastin into a
15 three-dimensional support structure wherein said
tropoelastin material is combined with a stromal
support matrix populated with actively growing stromal
cells.

59. The method of claim 56, wherein said stromal
20 support matrix comprise fibroblasts.

60. The method of claim 56, which further
includes the step of forming a cellular lining of human
cells on one of the major surfaces of said tropoelastin
layer.

25 61. The method of claim 56, wherein said cells
which are employed to form such a lining are at least
one of endothelial cells, epithelial cells and
urothelial cells.

62. The method of claim 56, which further
30 includes the step of forming an tropoelastin

biocompatible inner lining for mechanical human structures to ensure their continued internal use in a human body.

5 63. The method of claim 56, wherein the biocompatible inner lining is employed in heart valves, heart implants, dialysis equipment, or oxygenator tubing for heart-lung by-pass systems.

10 64. The method of claim 56, which includes the step of incorporating a drug into said biomaterial thereby decreasing the need for systemic intravenous or oral medications.

65. A tropoelastin biomaterial and tissue composite product, which comprises:

15 a layer of tropoelastin biomaterial having a first and second outer major surface;

a tissue substrate having a first and second outer major surface; and

20 an energy absorbing material, which is energy absorptive within a predetermined range of light wavelengths, disposed on one of said first and second outer surfaces of the tropoelastin biomaterial in an amount which will cause fusing together of one of said first and second outer surfaces of the tropoelastin biomaterial and one of said first and second outer surfaces of said tissue substrate,

25 one of said first and second outer surfaces of the tropoelastin biomaterial and the tissue substrate being fused together by said energy absorbing material which penetrates into the interstices of said tropoelastin biomaterial.

30

66. The method of claim 65, which further includes the step of employing tropoelastin material for use in replacement or repair of bladders, intestines, tubes, esophagus, ureters, arteries, veins, stomachs, lungs, hearts, colons, skin, or as a cosmetic implantation.

67. The method of claim 65, which further includes the step of forming an tropoelastin into a three-dimensional support structure wherein said tropoelastin material is combined with a stromal support matrix populated with actively growing stromal cells.

68. The method of claim 65, wherein said stromal support matrix comprise fibroblasts.

69. The method of claim 65, which further includes the step of forming a cellular lining of human cells on one of the major surfaces of said tropoelastin layer.

70. The method of claim 65, wherein said cells which are employed to form such a lining are at least one of endothelial cells, epithelial cells and urothelial cells.

71. The method of claim 65, which further includes the step of forming a tropoelastin biocompatible inner lining for mechanical human structures to ensure their continued internal use in a human body.

72. The method of claim 65, wherein the biocompatible inner lining is employed in heart valves,

heart implants, dialysis equipment, or oxygenator .
tubing for heart/lung by-pass systems.

73. The method of claim 65, which includes the
step of incorporating a drug into said biomaterial
thereby decreasing the need for systemic intravenous or
oral medications.

74. A method for producing a tropoelastin
biomaterial capable of being fused onto a tissue
substrate comprising:

providing a layer of tropoelastin biomaterial
having a first and second outer major surface; and
applying an energy absorbing material, which is
energy absorptive within a predetermined range of
light wavelengths, to a selected one of said first and
second outer surfaces of the tropoelastin biomaterial
in an amount which will cause fusing together of one of
said first and second outer surfaces of the
tropoelastin biomaterial and an outer surface of said
tissue substrate, said energy absorbing material
penetrating into the interstices of said tropoelastin
biomaterial,

the selected one of said first and second outer
surfaces of the tropoelastin biomaterial being capable
of fusing together with the outer surface of the
tissue substrate by irradiating the energy absorbing
material with light energy in a predetermined
wavelength range with an intensity sufficient to
facilitate said fusing together.

75. A tropoelastin biomaterial capable of being
fused onto a tissue substrate comprising:

a layer of tropoelastin biomaterial having a first and second outer major surface; and

an energy absorbing material, which is energy absorptive within a predetermined range of light wavelengths, applied to a selected one of said first and second outer surfaces of the tropoelastin biomaterial in an amount which will cause fusing together of one of said first and second outer surfaces of the tropoelastin biomaterial and an outer surface of said tissue substrate, said energy absorbing material penetrating into the interstices of said tropoelastin biomaterial,

the selected one of said first and second outer surfaces of the tropoelastin biomaterial being capable of fusing together with the outer surface of the tissue substrate by irradiating the energy absorbing material with light energy in a predetermined wavelength range with an intensity sufficient to facilitate said fusing together.

0879770-020393

aga
a''

ADD
E28